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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/582,779	07/03/00	POMPEJUS	M 48715

HM12/0424

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EXAMINER	
GANSHEROFF, L	
ART UNIT	**PAPER NUMBER**
1636	10

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/582,779	Applicant(s) POMPEJUS ET AL.	
	Examiner Lisa Gansherοff	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2000 and 19 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *9 and 13* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☒ Other: *detailed action* .

DETAILED ACTION

Pending claims: 1-15.

Response to: Preliminary Amendments filed 03 July 2000, 05 January 2001, 19 March 2001.

Specification

The disclosure is objected to because of the following informalities:

Throughout the disclosure, the terms "[sic]" and "[lacuna]" appear, as for example on page 3, line 4, page 4, line 20, page 13 line 5, and so forth. It is not clear what these terms are to mean, and it is not clear if they are intended to be in the specification. Please explain/clarify.

There does not appear to be a Brief Description of the Drawing section in the specification, although a drawing was submitted.

Appropriate correction is required.

Sequence Compliance

Acknowledgement is made of the receipt of a paper copy and computer readable form of the sequence listing and of the Applicant's statement that these are the same and contain no new matter. The sequence listing from the computer readable form has been entered.

Claim Objections

Claims 9 and 13 are objected to because of the following informalities: Claim 9 could be clarified by using parallel construction for the wording of the method steps. For example, wording such as "introducing this modified gene" could replace "this modified gene is

introduced", and wording such as "selecting these microorganisms" could replace "these microorganisms are selected". In claim 13, the phrase "is inserted as other gene" appears to be missing something between "as" and "other". Appropriate correction is required.

Claim Rejections - 35 USC § 112 and 35 USC § 101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the phrase "derive from". This phrase renders the claims indefinite because the nature and number of derivative steps are not defined, and thus the metes and bounds of the claims are not known.

Claims 14 and 15 provide for the use of a gene sequence, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14 and 15 are rejected under 35 U.S.C. 101 because the claimed recitation of a

use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims do not recite that the gene or amino acid sequence has been isolated from or otherwise altered from its naturally-occurring form in nature in an Ashbya gossypii cell. See MPEP 706.03(a)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Since the word "gene" refers not only to a coding sequence but also to an entire genomic structure (including introns and all regulatory regions upstream and downstream of coding sequences), and since the entire genomic structure of a representative number of eukaryotic

"genes" is not known, claim 10 is subject to a rejection for an inadequate written description. It is suggested that the word gene be replaced with terminology such as "nucleic acid sequence" or other terminology.

It is noted that the word "gene" is also used in the claims to refer to the orotidine-5'-phosphate decarboxylase gene of SEQ ID NO:1 and to refer to a gene of riboflavin synthesis. Based on the specification (for example, pages 4, 12, and 14), the Examiner is interpreting that SEQ ID NO:1 is a fully functional sequence from genomic DNA that is sufficient for expression of the orotidine-5'-phosphate decarboxylase protein. If this is not the case, for example, if SEQ ID NO:1 does not include sufficient transcriptional regulatory information for gene expression or is otherwise lacking an element of a "gene", then the word gene should not be used to refer to SEQ ID NO:1. The Examiner is also interpreting that entire genomic sequences for riboflavin synthesis genes are known, based on Applicant's IDS; if this is not the case, then the word "gene" should not be used in claim 13. It is requested that Applicants confirm or otherwise respond to these interpretations.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-13 are drawn to a genus of orotidine-5'-phosphate decarboxylase genes having the sequence of SEQ ID NO:1 or its homologs which have at least 80% homology, or amino acid

sequences encoded by the genes. All of the claims except claim 2 also encompass "homologs" from any organism. The specification only describes SEQ ID NO:1, which is the orotidine-5'-phosphate decarboxylase gene from *Ashbya gossypii*. In a search of the prior art, the Examiner was unable to find a gene having at least 80% homology with SEQ ID NO:1. Thus, only one species of the claimed genus appears to have been known at the time of the invention; no genes having at least 80% homology to SEQ ID NO:1 were found in the prior art. Further, based on the wording of claim 4, which specifically recites an amino-acid sequence which comprises an enzymatically active protein, it appears that the other claims lack a correlation between structure and function. That is, the homologs of the other claims apparently need not encode enzymatically active proteins. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, including genes encoding both active and non-active proteins, and also including genes from any organism, SEQ ID NO:1 alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Gansheroff whose telephone number is (703) 605-1203. The examiner can normally be reached 9 AM - 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached at (703)

308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242 for regular communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Dianiece Jacobs whose telephone number is (703) 305-3388 or to the receptionist whose telephone number is (703) 308-0196.

LG
April 19, 2001

JAMES KETTER
PRIMARY EXAMINER